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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,473	03/26/2002	Kwang-Hoe Chung	0136/OK432USO	1138

7590

12/20/2004

Darby & Darby
805 Third Avenue
New York, NY 10022

EXAMINER

BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,473	CHUNG ET AL.	
	Examiner	Art Unit	
	Gabriele E. BUGAISKY	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/9/2002</u> . | 6) <input checked="" type="checkbox"/> Other: <u>copy of PTO-1390</u> . |

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DETAILED ACTION

Priority

Receipt is acknowledged of papers filed under 35 U.S.C. 119 (a)-(d) based on an application filed in WIPO on 26 July 2000. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge the filing of any foreign application. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date. The Examiner cannot grant priority until a new declaration claiming priority is filed. It is also noted that Applicants have stated on PTO-1390 that the international filing date of PCT/KR00/00809 was 26 March 2002. Again, priority cannot be granted until this matter is resolved.

Specification

The statement submitted 3/26/2002 regarding public availability of the deposited cell line in compliance with 37 C.F.R. 1.801-1.809 is noted.

The disclosure is objected to because of the following informalities: the appropriate SEQ ID NO; does not appear immediately subsequent to all sequences (e.g., p 7, lines 24, 27)

Appropriate correction is required

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The use of trademarks [e.g., SEPHADEX (page 11, line 10), ROBOCYCLER (p 13, line 24) SEPHAROSE (page 15, line 9), etc.] has been noted in this application. Each should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

First, it is noted that the name of a protein does not define it in terms of structure or function. In fact, the name of a protein is arbitrarily assigned by the inventors thereof, and may change over time as more is discovered about the protein. For example, interleukin-1 is also

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known as lymphocyte activating factor, endogenous pyrogen, leucocyte endogenous mediator, mononuclear cell factor, and catabolin (see Callard et al).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 1-2, it is not clear what the term "represented as" means, whether the claimed compound comprises or consists of the recited sequences or whether the recited sequences are an example of a saxatilin, which is a protein component of venom of *Agkistrodon saxatilis*,

With respect to claim 3, it is not clear what the recited fraction is active as. It is suggested that, e.g., disintegrin activity be recited.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: collecting either a cell lysate or supernatant prior to application to a hydrophobic column. It makes no sense to the examiner that a protein can be purified from cells by applying the culture-containing microorganism directly to a hydrophobic column.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2, and 11-12 are rejected under 35 U.S.C. 102(a) as being anticipated by HONG *et al*. As stated above, the Examiner cannot yet grant priority. The reference has but 4 of the 8 inventors and is thus considered “by another”. The reference provides for the purification of saxatilin and the cloning of recombinant saxatilin, and tests for its activity as a disintegrin (anti-platelet agent. It also discusses the possibility that Saxatilin may suppress the suppression of tumor growth. With respect to claim 12, intended use bears no patentable weight in a composition claim, when nothing differentiates the composition from the prior art. Thus, the anti-plate agent comprising saxatilin of the reference anticipates the anti-tumor agent of claim 12

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 -10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong *et al*. in view of HAWROT (US patent 6753315). The reference is discussed above. It does not provide for the specific vector and process of preparing recombinant saxatilin. HAWROT

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teaches that α -bungarotoxin has 5 disulfide bridges which present problems in correct folding when expressed in *E. coli* (see e.g., column 13, line 2-6) yet when α -bungarotoxin is made in the host cell *Pichia pastoris* using the expression vector pPIC9K, it has properties identical to that purified from venom, and does not require any additional refolding (see, e.g., column 19).

Since the saxatilin of HONG *et al.* has 12 cysteines, it is likely that recombinant expression of the protein would result in an improperly folded molecule with minimal disintegrin activity. In order to optimize yield and amount of correctly folded active saxatilin, one of skill in the art would have found it obvious to use the expression system utilized by HAWROT, with a reasonable expectation of success. With respect to the culture conditions recited in claim 9, methanol is commonly used as a carbon source for *Pichia*.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chen *et al.* fractionate by electrophoresis venoms of *Akgistrodon*, including *A. saxtlis*.

Smith *et al.* screen 32 snake venoms for inhibitory activity of platelet adhesion to collagen.

Akgistrodon (= *Gloydius*) *saxatilis* is not tested.

Kogan *et al.* fractionate venom from several different snakes including *A. saxatilis* by HPLC, (Fig. 1) and shows the pH optimum of the protein C activators (Table 1), but the relationship of their activators to the instant disintegrin is unknown.


No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (571) 272-0945. The examiner can normally be reached on Tues.- Fri 8:15 AM-1:45 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1653

533 Rec'd PCT/PTO 11 JUL 2002

FORM PTO-1390 (REV. 9-2001)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER 0136/OK432US0
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. APPLICATION NO. (If known, see 37 CFR 1.5 10/089,473 filed 3/26/02
INTERNATIONAL APPLICATION NO. PCT/KR00/00809	INTERNATIONAL FILING DATE 26 March 2002	PRIORITY DATE CLAIMED 1FD of PCT/KR00/00809	
TITLE OF INVENTION NOVEL PROTEIN DERIVED FROM AGKISTRODON SAXATILIS EMELIANOV AND PROCESS FOR PREPARING THE SAME			
APPLICANT(S) FOR DO/EO/US Kwang-Hoe CHUNG; Doo-Sik KIM; Sung-Yu HONG; You-Seok KOH; Young-Doug SOHN; Weon-Kyoo YOU; Yang-Soo JANG; Chin-Kyu HUH			
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:			
<p>1. <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31).</p> <p>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> has been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p>a. <input type="checkbox"/> is attached hereto.</p> <p>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p>Items 11 to 20 below concern document(s) or information included:</p> <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A FIRST preliminary amendment.</p> <p>14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>17. <input checked="" type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT-Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input checked="" type="checkbox"/> Other items or information:</p> <p>1. Notification of Missing Requirements</p> <p>2. Submission of Nucleotide And/Or Amino Acid Sequence Listings Under PCT Rule 13 ter.1; paper copy of Sequence Listing</p>			
<p>EXPRESS MAIL CERTIFICATE</p> <p>Date: 7/11/02 Label No. 15766635</p> <p>I hereby certify that, on the date indicated above, this paper or it was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.</p> <p>Beck Beck</p>			